authority to provide for notice and opportunity for public hearing on the establishment of guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(f) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information.

[58 FR 17106, Apr. 1, 1993]

§ 5.30 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act; section 6 of the Fair Packaging and Labeling Act; section 9(b) of the Federal Caustic Poison Act; and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(4) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(5) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Directors, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the Public Health Service Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing pursuant to the provisions of part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of § 16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Associate Commissioner for Health Affairs.

(2) The Director and Deputy Directors, CFSAN.

(3) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors, CDRH.

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Director, CBER, and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

[48 FR 8440, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8316, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997]

§5.31 Petitions under part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter for a stay of an effective date in §201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors of the Offices of Biological Product Review and Biologics Research, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Biological Product Review and Biologics Research, CBER.

(2)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iv) The Director and supervisory consumer safety officers, Pilot Drug Evaluation Staff, Office of the Center Director, CDER.

(b) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter requesting in vitro test modifications under §331.29 of this chapter:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(c) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in §211.132, §700.25, or §800.12 of this chapter for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director and Deputy Directors, Center for Devices and Radiological Health.

(d) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter requesting exemption from the general pregnancy-nursing warning for over-the-counter (OTC) drugs required under §201.63 of this chapter, requesting exemption from a general overdose warning required under §330.1(g) of this chapter, and requesting exemption from OTC drug administrative procedures under §330.10 of this chapter:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(e)(1) The following officials are authorized to issue 180-day tentative responses to citizen petitions on food and cosmetic matters under §10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center: